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The Curious Case of Thrifty Patent Procurement

By: **Clifford M. Davidson, Esq.**

Throughout the past few years, the pharma industry has steadily attempted to move toward less-costly patent procurement. This move is being made not only by strapped-for-cash drug delivery and specialty pharma concerns, but by big pharma as well. The author is often astounded by Pharma companies that are willing to spend millions of dollars to litigate a patent, but balk at the initial cost of obtaining the best patent possible where future litigation is possible or even inevitable. The following provides the benefits and pitfalls of such strategies from the viewpoint of the undersigned patent attorney.

OFFSHORE PATENT DRAFTING

A trend has emerged over the past few years based on the aggressive marketing of patent services by patent agencies based in India. Obviously, the pay scale is much lower in India. There is no shortage of highly educated scientists in India, however. These patent agencies have been offering their services to US law firms (for outsourcing overflow patent work) and directly to Pharma concerns. Any number of services is being offered, ranging from patent drafting to patentability and invalidity searches.

One issue that arises from the use of such services concerns the exportation of new technology across US borders without the permission of the US Government. Typically, a US patent application is awarded a foreign filing license during the preliminary stages of US patent prosecution (typically within 6 months of filing) as part of the completion of formalities. However, published in the

Federal Register (73 Fed. Reg. 42781) this past summer, it was reiterated that the exportation of subject matter abroad pursuant to a USPTO-issued foreign filing license is limited to purposes related to the filing of foreign patent applications (see 37 C.F.R. § 5.15). The Notice states unequivocally that a foreign filing license from the USPTO does not authorize exporting of subject matter abroad for the preparation of patent applications to be filed in the US. Those who wish to export subject matter for the purpose of having a patent application prepared for US filing are advised to contact the Bureau of Industry and Security (BIS) at the Commerce Department in order to secure the appropriate clearances.

The advantage of offshore patent preparation in a low pay-scale country is clear - significantly lowered fees. But at what cost? The pharmaceutical field is littered with relatively worthless patents written by technicians who understood the technology but were not particularly patent savvy. There is a difference between one who is knowledgeable about a technology and one who is knowledgeable about the technology and understands how to write patent claims that maximize the value of that technology given the many forks in the patent-drafting road - Orange Book listability, capturing potential design-around strategies, covering all important aspects of the invention in a variety of different strategically designed claims, etc. The other factor to consider in offshore patent preparation is the relative hassle of obtaining Government permission to export the information, and the lack of a personal connection between the inventor(s) and patent draftsman.

FIXED-COST PATENT FILING

A number of companies are seeking to control patent costs by seeking “fixed” costs for the preparation of a patent application by outside patent firms, and further seeking to control the costs of the subsequent patent prosecution by seeking “price-fixed” patent amendments and related documents. Controlling costs in an abysmal economy is a necessity, without question. However, buyer beware. Outside counsel working on a fixed budget cannot possibly spend as much time on a fixed budget as they can on a less stringent budget, nor can they carefully consider all potentially important issues.

The fixed-cost model can easily lead to less interaction between inventor and patent counsel resulting in relevant information being left out of the patent filing. This can take the form of incomplete disclosures that do not meet the requirements of the USPTO regarding (a) written description (the application must adequately identify that subject matter that the inventor deems to be his/her invention), (b) best mode (the application must describe the “best mode” of carrying out the invention), and (c) enablement (the patent application must provide a disclosure that enables one of ordinary skill in the art to practice the invention). These problems, if present upon the filing of a patent application, cannot be cured later - new information is considered “new matter” by the patent offices of the world, and can only be added by filing a new patent application. Given the fact that most patent filings now publish within 18 months of original filing date, and most applications do not receive a first examination anywhere prior to publication, it is likely that the defective filing will become “prior art,” affecting the ability of the inventor to patent an application with corrected and/or additional information, which is not entitled to the original filing date. Worse yet, such actions are unlikely to correct foreign filed applications, or if possible may lead to incurring huge costs for foreign filings anew.

This discussion leads to the problems one faces in obtaining European patents. The European Patent Office (EPO) has different standards for patentability than the USPTO. Moreover, and just as importantly, the EPO has different standards for making claim amendments. Claim amendments in the EPO must be literally supported by the specification - one cannot wordsmith to arrive at a description taking the general disclosure of an application to describe a feature in the European claims that is different than prior art relied upon by the European Examiner. While it is not possible for a patent practitioner to predict every issue that can arise during patent prosecution and include suitable descriptive language to address such issues, the less time and energy put into the drafting of a patent application, the more difficult and costly it becomes to overcome such issues later during prosecution of that application.

The fixed-cost model also does not lend itself well to the outside patent counsel being able to identify and cover potential third-party design-around strategies. Does this mean that I am steadfast against fixed patent costs in all situations? No. To say that would be ignoring the current economic climate and the needs of industry to control costs at a time when funding is difficult to obtain, at best. I do have a few suggestions for companies working under such financial constraints with respect to patent filings.

First, I would suggest that the inventor or another in-house person who understands the technology and has some basic understanding about patents draft as detailed a disclosure as possible - a few sentences and copies of lab notebook pages does not suffice. The more information provided to the outside patent attorney, the less time they need to spend identifying what is missing - and the more time they can spend on drafting suitable patent claims.

Second, I suggest the company have in-house patent searches performed, eg, on free on-line databases, such as the USPTO search engine or Google patents. The search strategy

and results should be provided to the patent attorney as well. This enables the outside patent attorney to better identify the potential prior art and to better identify the proper claim scope.

Third, in my opinion, fixed-cost patent work should be limited to inventions that are not crucial to the success of the company. In addition to covering key aspects of new or developing proprietary technologies, patent applications are often filed and maintained for alternative processes of manufacturing, alternative formulations, compositions that are not going to be developed commercially, and the like. Those types of patent filings are more the candidate for limiting costs, in the author's opinion.

THE "I CAN DRAFT IT MYSELF" SYNDROME

I know many very smart people in Pharma who are patent savvy. Being patent savvy places one in a better position to contribute to the patent disclosure and the scope of the ultimate claims. Some inventors that I know are quite capable of writing a strong disclosure and claims. On the other hand, inventors should be careful about assuming that being patent savvy equates to being able to act as their own patent counsel. Some pitfalls that I have seen throughout the years includes choosing what to include and not include in the patent specification, not adequately explaining in useful language important differences between the new technology and the prior art, not providing adequate definitions of important parameters, lack of a clear understanding of how the prior art may be applied against a new invention, the devising of a successful strategy to obtain useful patent protection, and not adequately considering the full scope of the invention to ensure that possible alternatives are encompassed. Additionally, the drafting of claim language must be done carefully and with thought as to the use of each word and phrase and how they should be interpreted (or might be

misinterpreted) by others. This is not just a problem for inventors - patent attorneys who are not familiar with the technology, the field, or are otherwise not savvy with respect to the invention or patent drafting suffer from the same problems.

Why is this important? One of the key moments during patent litigation is when the court determines what the claims mean, commonly referred to as "claim construction." The very words included in the specification to explain the invention (and the claims), or lack thereof, can have a profound effect on the scope of claim coverage. In *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005), the Federal Circuit held among other things that the words and descriptions in the specification can be used to (narrowly) interpret the claims in certain situations.

That is not to say that patent attorneys do not welcome detailed reports or drafts of an invention disclosure. Certainly, this provides the patent attorney with the tools needed to draft a valuable application, and is a cost-cutting measure for the client. On the other hand, I have spent many hours "rehabilitating" patent drafts written by inventors - this can actually wind up being more costly than letting the patent attorney start working with the invention at an early stage.

The "I can draft it myself syndrome" can be just as dangerous during prosecution. In *Festo Corp. v. Shoketsu Kinzoku Co. Ltd.*, 535 U.S. 722 (2002), the Supreme Court held that there is a presumption that a claim amendment was made for a reason related to patentability, with limited avenues to rebut this presumption. Festo significantly expanded the doctrine of prosecution history estoppel, which in turn means that any changes made to the claims has the potential to turn into a reason why the alleged infringing product doesn't infringe the claim(s) under the Doctrine of Equivalents. Everything one writes in a document that goes to the patent office becomes a public record. Well-intentioned arguments and claim changes don't always play out well, even if a patent

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ultimately results: unnecessary estoppels to patent claim coverage may be avoidable via the use of experienced patent counsel.

A well-drafted patent application is also crucial in view of the Supreme Court's decision concerning obviousness in *KSR v. Teleflex*, 550 U.S. 398 (2007). In *KSR*, the Supreme Court held that in order to demonstrate obviousness it was not necessary to satisfy the teaching/suggestion/motivation (TSM) test, and that an invention could indeed be found to be obvious in view of the "obvious to try" standard. Although the full impact of the *KSR* decision is still in its infancy, it is already quite clear to patent practitioners that there is a real need to develop a patentability strategy prior to filing.

IS HIGH COST ALWAYS BETTER?

High cost is certainly not always better, and the bigger the firm does not necessarily translate into a better product. It is important for the company that does not have in-house patent counsel to consider whether they have developed a useful patent strategy. Are filings being undertaken prior to publication of articles or disclosure to third parties without the benefit of confidentiality? Are decisions being made to control costs with respect to non-core technology? Is the patent strategy being vetted at an early stage, or is it reactionary to situations that arise when it may be too late?

SUMMARY

It is probably not the best time to argue that resources should be allocated to intellectual property during the midst of a deep recession. However, in the end, it is often the intellectual property that has a strong hand in determining the value of a new product, or even the company itself. Therefore, well-

reasoned decisions should be made about how to allocate funds for patent filings, and when to cut corners... and when not to. If I have provoked thought about this topic via this article, then my purpose has been served. ♦

BIOGRAPHY



Clifford M. Davidson, Esq. is a founding partner at Davidson, Davidson & Kappel, LLC, an Intellectual Property law firm with offices in New York City and Frankfurt, Germany. He counsels pharmaceutical clients in pharmaceutical patent-related

matters, including patent prosecution, freedom to operate and infringement opinions, due diligence and tech-transfer, and litigation (including ex parte and inter partes proceedings worldwide). He has assisted specialty pharma and drug development companies to create significant patent portfolios, and the patents he has written and the patent portfolios he has created have been recognized as creating significant value for his clients. He has written patents covering virtually all areas of drug development, and has pioneered strategic patent focus on the pharmacokinetic profiles and the pharmacologic activity of drug/drug formulations. Mr. Davidson earned his BS in Pharmacy and his JD from Rutgers University and is a member of the New York and New Jersey Intellectual Property Law Associations, the American Pharmaceutical Association, and The Controlled Release Society. His area of expertise includes new chemical entities; new pharmaceutical formulations (including controlled-release oral dosage forms, injectables, transdermals, ophthalmics, inhalation, intranasal, sublingual, suppository, and implantation administration); new combinations of previously known drugs; new modes of administration of previously known drugs; method of treatment; pharmaceutical excipients; and methods of preparation.